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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MATTHEWS, WILLIAM H	

ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/673,528	WANG, LIXIAO	
	Examiner	Art Unit	
	HOWIE MATTHEWS	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,35,91-98,100-116,119-125 and 127-135* is/are pending in the application.

4a) Of the above claim(s) *102-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,91-98,100,101,105-116,119-125 and 127-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/18/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new grounds of rejection set forth below.

Regarding Scott teaching a plurality of layers, Examiner notes Scott's disclosure of a plurality of polymer materials meets a plurality of layers. See, for example: column 6, lines 4-5, column 7, lines 55-59, column 8 lines 58-60.

Regarding the coated end surfaces, see new grounds of rejection set forth below.

Regarding Berg in view of Scott, Nolting, Jang, Richter, Wallsten, Applicant appears to merely argue the number of references relied upon and fails to suggest how the references fail to render the claimed invention obvious. However, reliance upon a certain number of references does not weigh against obviousness. See MPEP 2145(V).

Regarding the teachings of Wallsten or Richter, Examiner maintains "Articulated reasoning" was provided (i.e. to provide an even expansion diameter). Richter teaches this benefit at abstract, figures 1-4 (including the cover figure), and the respective description at columns 5-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,91,92,94,96-98,100-101,108-111,113,115-116,119-120,124-125,127-128,130-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. USPN 5383928 ("Scott") in view of Myers et al. USPN 5700285 ("Myers"), Richter USPN 5807404 ("Richter"), Nolting et al. USPN 6488701 ("Nolting"), and Applicant's admission at page 4 lines 1-5 or paragraph 0015 of the published application.

Scott disclose a balloon expandable metal stent comprising a sleeve coating of a polymer/drug mixture which may be placed on one stent end such that the middle is free of any polymer/drug (column 6 lines 41-45). The coating may include an RGD peptide containing compound, a plurality of drugs, and plurality of polymers which is interpreted by examiner to meet the limitations of a plurality of different layers (see column 6, lines 4-5, column 7, lines 55-59, column 8 lines 58-60).

Scott is silent as to the stent comprising end cells which are larger or more flexible than the middle cells (claims 1,108,109,124, and 134). Richter teach stent patterns comprising larger and more flexible end cells (See abstract, figures 1-4, and respective description at c5-c7) in order to provide an even expansion diameter to reduce likelihood of thrombosis or puncturing the vessel wall. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent pattern of Scott to include the varying cell sizes and flexibility taught in Richter in order to provide a safer, non-flaring expansion shape.

Scott is silent as to the stent comprising self expanding nickel titanium or stainless steel (claims 101,120,124,134). However, Applicant admits at page 4 lines 1-

5 (or para [0015] of the published application) that stents of the self expanding and balloon expandable type are well known in the art. Examiner further takes Official Notice that nickel titanium alloys and stainless steel materials were well known in the stent art at the time of the invention. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent materials of Scott to use self expanding nickel titanium or stainless steel in order to utilize known materials and expansion techniques to secure the stent in a blood vessel.

Scott is silent as to directly adhering the sleeve coating material to the metal surface of the stent. Myers teach stents with sleeve coatings wherein the material may be affixed to the stent by thermoplastic adhesive and the coatings remained intact after collapsing and enlarging the stent (see abstract and examples). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent in Scott to include adhesion points, as taught in Myers, to secure the sleeve position and prevent migration of the sleeve from the stent.

Regarding each independent claim requiring the end surface to be coated, Myers teaches at Figure 8 and its description in Example 3 that it is well known to coat the end surfaces of a stent. Further, Nolting teach benefits of fully encapsulating a stent with a coating to enhance bond strength (column 6 lines 28-37). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent in Scott to include coated ends, as taught in Myers and Nolting, to enhance bonding of the sleeve to the stent.

Regarding claim 127, the edges of the frame taught by Richter above may be square or triangular which comprise edges and would be covered by the sleeve of Scott.

Regarding claims 128,130,133, and 135, see Scott example at column 8 line 58-60, whereby a layer of EVA and layer of PTFE are disposed on a stent.

Claims 1,91-98,100-101,105-116,119-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. USPN 5464650 ("Berg") in view of Scott et al. 5383928 ("Scott"), Nolting et al. USPN 6488701 ("Nolting"), Jang USPUB 2004/0106985 ("Jang"), Richter USPN 5807404 ("Richter"), Applicant's admission at page 4 lines 1-5 or paragraph 0015 of the published application, and Kunz et al. USPUB 20020086896 ("Kunz").

Berg disclose self expanding or stainless steel, balloon expandable (claims 100-101,119-120) stents (c3:28-50) comprising a coating of a polymer and drug, wherein the coating is applied in a plurality of layers of the same coating material (claims 92,93,111-112,114-115,128-129). The coating adheres to the stent struts, and expands with the stent, so is thus considered a bioadhesive, gel-like, and having apertures/perforations as broadly claimed (claims 91,95,96,110).

Regarding claims 1, 108, 109, 132 and 134, Berg is silent as to providing the coating on an end portion and not on a middle portion of the stent. Each of Scott and Nolting teach coated stents for delivering drugs to the blood vessel or vessel lumen wherein the drug delivery coating is placed only on an end portion of the stent in order

to provide a targeted localized delivery. See Nolting col. 7:50-57 and Scott col. 5:26-33 and c6:41-45. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the drug delivery stent of Berg to include the coating at only one or both end portions, as taught by Scott and Nolting, in order to provide a targeted delivery of therapeutic agents.

With further regard to claims 1, 108, 109, and 134 which require the end surface of the end portion to be coated, it is noted that Berg disclose the coating may cover both the inner and outer surfaces (c3:49-51) may be immersed (c4:21-24). Thus it appears inherent that the end surface of the coated end portion would be coated as well. If not inherent, Nolting teach coating the entirety of a stent strut (encapsulation) in order to enhance bond strength of the coating. Thus if not inherent, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent of Berg to include a coated end surface portion as taught in Nolting in order to enhance bond strength of the coating.

Berg disclose the stent may take the form of any stent design (column 3 lines 28-35) such as Palmaz 4800882 which includes cells but is silent as to the stent comprising end cells which are larger and more flexible than the middle cells (claims 1,108,109,124, and 134). Richter teach stent patterns comprising larger and more flexible end cells (See abstract, figures 1-4, and respective description at c5-c7) in order to provide an even expansion diameter to reduce likelihood of thrombosis or puncturing the vessel wall. It would have been obvious to one of ordinary skill in the art at the time

of the invention to modify the stent pattern of Berg to include the varying cell sizes and flexibility taught in Richter in order to provide a safer, non-flaring expansion shape.

Berg is silent as to the self expanding stent comprising nickel titanium material (claims 124,134). However, Applicant admits at page 4 lines 1-5 (or para [0015] of the published application) that stents of the self expanding and balloon expandable type are well known in the art. Examiner further takes Official Notice that nickel titanium alloys were well known self expanding materials in the stent art at the time of the invention. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent materials of Berg to use nickel titanium material in order to utilize known materials to self expand the stent in a blood vessel.

Regarding claims 94, 113, and 130, Berg is silent as to providing a plurality of coating layers having different coating materials. Scott teach at lines 4-5 of col. 6 that plurality of layers may comprise different materials in order to achieve a desired release profile. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the drug delivery stent of Berg to include a plurality of layers having different materials, as taught by Scott, in order to achieve a desired release profile.

Regarding claims 97,105-107,116, and 121-123, Berg is silent as to specifically using drugs such as RGD peptide containing compounds, tranilast, trapidil, or probucol. Berg do disclose the drug used may be one of a plethora of drug classes at col. 2 lines 55-62. Jang teaches at paragraphs [0344-0346] an expandable stent comprising therapeutic compounds which may include anti proliferative agents, inhibitors of

vasoactive mechanisms inflammatory actions, or RGD peptide containing compounds in order to promote endothelialization. Tranilast, Trapidil, and Probucol are known therapeutic inhibitors or anti-proliferative agents in the art. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent disclosed by Berg, and modified by Nolting or Scott, to include RGD peptide containing compounds, Tranilast, Tropidil, or Probucol, as taught by Jang '985, in order to promote endothelialization.

Regarding claim 127, Berg discloses the stent may take the form of Palmaz 4800882 which includes edges (Figures 2A-2B).

Regarding claim 133, Berg as modified above is silent as to using PTFE polymeric coverings. Kunz teach at paragraph 0173 stents comprising PTFE coverings for delivery of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to use PTFE for the polymeric covering material, as taught by Kunz, with the Berg stent in order to utilize known covering materials to deliver a therapeutic agent from a stent.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOWIE MATTHEWS whose telephone number is (571)272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774